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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/670,781 | 09/27/2000 | Paul C. Daly | 4538US | 6751 |

7590 03/31/2004
MICHAEL W. HAAS, ESQ.
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EXAMINER

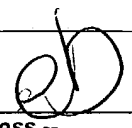
WEINSTEIN, STEVEN L

ART UNIT PAPER NUMBER

1761

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|---|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/670,781 | DALY, PAUL C. | |
| | Examiner | Art Unit |  |
| Steven L. Weinstein | 1761 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/15/04
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 7, 10, 12, 13, 15-17, 19+20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10, 12, 13, 15-17, 19+20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazure et al ('207) in view of Blass et al (2/91), Stevens et al (Jan/Feb/1999), Stevens et al (1997) and Frank (2000), further in view of Beckers ('746) and Hendriks et al ('242) further in view of Bublitiz (4,211,338) for the reasons fully and clearly detailed in the Office action mailed 3/13/02, paper no. 6 and Office action mailed 7/11/03, paper no. 9.

Claim 1 now recites that the cup shaped containers are individual, not attached to any other container. Support for this is seen in figure 2. However, such structure is conventional single serve or single use cup structure as shown by both Lazure et al and Beckers. Claim 1 also now recites that the cover is defined by a material that is less rigid than "a" material defining the cup shaped container such that the cover can be incrementally removed from the container. Such language is not seen to be supported by applicants disclosure. In any case, the cup assembly of Lazure et al comprises a "sheet like" closure and a thermoformed tray(col. 5, para. 3). A thermoformed tray will be more rigid than a sheet-like closure, which is designed to be peeled from the tray. These types of single serve or single use peelable covers/self supporting cups are notoriously well known in the art and have been seen used in food packaging and food service environments such as restaurant for many years. Bublitiz can be relied on as further evidence of a cover less rigid than the cup (the cover is flexible and flexes, the cup does not).

Claims 12,13, 15, 16, 17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blass et al (2/91), in view of Stevens et al (Jan/Feb 1999), Stevens et al (1997) and Frank (2000), further in view of Lazure et al ('207), Beckers ('746) and Hendriks et al ('242), further in view of Bublitz (4,211,38) and Wisconsin State J. (2/6/91, p.4A) for the reasons fully and clearly detailed in the Office action mailed 7/11/03, paper no. 9 and 3/13/02, paper no. 6.

Bublitz is relied on as further evidence of cups for use with drug doses or food use. Claims 12 and 17 now recite that a pacifier is dipped into the solution and the solution is thus administered to the patient by placing the sucrose solution coated pacifier into the patients mouth. As evidenced by Wisconsin State J., it was well established to administer a sugar solution for its analgesic properties by dipping a pacifier into a sugar solution and placing it in the patients mouth.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6, 7, and 10 are rejected under 35 USC 112, first paragraph for containing New Matter. The recitation discussed above, that is, that the cover is less rigid and can be incrementally removed does not appear to be supported by the specification.

All of applicant's remarks filed 1/15/04 have been fully and carefully considered but have not been found to be convincing essentially for the reasons previously detailed.

Contrary to what has been urged, the fact that it was notoriously conventional to package medicines in single use (or dose) conventional containers clearly does suggest placing the recited

food/medicinal (i.e. an analgesic) in the conventional container for its art recognized and applicant's intended use; that is to provide a single dose, single use amount of conventional product. It one reference actually suggested placing the conventional composition in the conventional container, then the rejection would have been under anticipation (35USC102) not obviousness (35USC 103).

On page 8 of the amendment, urgings of how the conventional sucrose solution is to be administered is not relevant to the container claims. However, contrary to what has been urged, the use of a pacifier to administer the conventional sucrose solution after it has been dipped into the solution was conventional as evidenced by Wisconsin State Journal.

On page 8, reasons are given why one would not want to employ the recited conventional containers with the sucrose solution. These urgings are not convincing. The art taken as a whole teaches medicinals and foods in single dose/single use containers, so that applicant was not the first to use such a system. As with any system, one must weigh the pros and cons of the system. Since single dose/single use systems are wide spread, their benefits must clearly outweigh negatives. Finally, the discarding of an unused portion of product has been addressed previously.

Food Engineering and New Food Products In Japan are cited as art of interest to show single portions/single serve units of liquid sweetener and San Francisco Examiner is relied on to show single portions of sugar solution used for medicinal reasons.

Any inquiry concerning this communication from the examiner should be directed to Steven Weinstein whose telephone number is (571) 272-1410. The examiner can generally be reached on Monday-Friday 7:00am to 3:30 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (571) 272-1201.

S. Weinstein/af

March 17, 2004


STEVE WEINSTEIN
PRIMARY EXAMINER 1761
3/24